UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,732	04/04/2002	Viktoria Petrovna Yamskova	P67704US0	9698

136 7590 08/30/2006

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,732	YAMSKOVA ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 6/15/06, in which applicant amended claim 4.

Claims 4-6 are pending.

Claim Rejections - 35 USC § 112

Claims 4-6 are/stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record which are restated below.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to glycoproteins extracted from blood serum, liver, thymus or eye, the glycoprotein having an apparent molecular weight of 10-45 kDa and having specific biological activity to influence viscoelastic properties of hepatocyte membranes in ultra low doses from 10^{-12} to 10^{-29} mol/liter.

The breadth of the claims is excessive with regard to claiming a glycoprotein having specific biological activity to influence viscoelastic properties of hepatocyte membranes in ultra low doses from 10^{-12} to 10^{-29} mol/liter. It is deemed that ultra low doses of this nature would fail to provide any therapeutic effect especially absent evidence to the contrary. Further, it is deemed that the ultra low doses of 10^{-12} to 10^{-29} mol/liter is an impossible concentration, which goes beyond the knowledge of scientific principals. It is deemed that, in a 10^{-29} mol/liter, that not even one molecule will be present since, according to Avogadro's number, one molecule is present in 10^{24} (parts).

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that example 5 of the instant specification shows the procedure of determining the effect of the glycoprotein on viscoelastic properties of hepatocyte membranes.

However, the examiner contends that ultra low doses of this nature would fail to provide any therapeutic effect, because in a 10^{-29} mol/liter, that not even one molecule will be present since, according to Avogadro's number, one molecule is present in 10^{24} (parts).

Claims 4-6 are/stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record which are restated below.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to glycoproteins extracted from blood serum, liver, thymus or eye, the glycoprotein having an apparent molecular weight of 10-45 kDa and having specific biological activity to influence viscoelastic properties of hepatocyte membranes in ultra low doses from 10^{-12} to 10^{-29} mol/liter, said specific biological activity to influence viscoelastic properties of hepatocyte membranes is determined by the amount of cellular nuclei released during dispersing according to the formula: Ea= 200%-(Non/Nk)x100%., a pharmaceutical composition comprising the glycoprotein and a method of using the glycoprotein, comprising administering the glycoprotein to a subject as a medicinal agent. It is deemed that ultra low doses of this nature would fail to provide any therapeutic effect especially absent evidence to the contrary. Further, it is deemed that the ultra low doses of 10^{-12} to 10^{-29} mol/liter is an impossible concentration, which

goes beyond the knowledge of scientific principals. It is deemed that, in a 10^{-29} mol/liter and lower, that not even one molecule will be present since, according to Avogadro's number, one molecule is present in 10^{24} (parts).

Finally, it is not described of what use is the glycoprotein as a pharmaceutical composition or medicinal agent , as no method steps are given.

Because the claims fail to show that applicant was in possession of the invention, it is deemed that the skilled artisan could not make or use the composition/ method instantly claimed.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that example 5 of the instant specification shows the procedure of determining the effect of the glycoprotein on viscoelastic properties of hepatocyte membranes.

However, the examiner contends that ultra low doses of this nature would fail to provide any therapeutic effect, because in a 10^{-29} mol/liter, that not even one molecule will be present since, according to Avogadro's number, one molecule is present in 10^{24} (parts).

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
8/23/06

RT

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600